K012861

FEB 0 5 2002

Appendix 8
Summary of Safety and Effectiveness

Submitter:

NeoMetrics, Inc.
15301 Highway 55 West
Plymouth, MN 55447
Telephone: (763) 559-4440
Fax: (763) 559-7676

Product:

Classification Name:	Catheter Guidewire (21 CFR 870.1330)
Common Name:	Guidewire, catheter guidewire, and wire guide
Trade/Proprietary Name:	Vascupuncture™ Access Wire

Substantially Equivalent Products:

Lake Region Manufacturing CCA Guidewires (K971322) and other commercially distributed devices.

Description:

This guidewire has a 0.0175" diameter and is available in lengths of 45-120 cm. It features gradual diameter changes in the distal section to facilitate vascular insertion and compatibility with various introducers and catheters. A variety of distal tapers impart different tip flexibilities.

Indications for Use:

For percutaneous vascular entry using the Seldinger technique.

Comparison To Substantially Equivalent Products:

Predicate devices have the same intended use and have similar designs and materials. NeoMetrics Access Wires and predicate devices were subjected to bench and biocompatibility testing to demonstrate equivalency in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2002

Mr. Gene Champeau
President
NeoMetrics, Inc.
15301 Highway 55 West
Plymouth, MN 55447

Re: K012861
Vascupuncture™ Access Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: November 28, 2001
Received: November 29, 2001

Dear Mr. Champeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

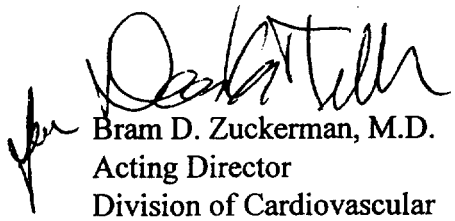
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012861

Device Name: NEOMETRICS VASCUPUNCTURE ACCESS WIRE

Indications For Use:

THE NEOMETRICS VASCUPUNCTURE ACCESS WIRE IS INDICATED FOR PERCUTANEOUS VASCULAR ENTRY USING THE SELDINGER TECHNIQUE.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012861